## REMARKS

The Office Action of October 14, 2008, has been carefully reviewed, and in view of the above amendments and the following remarks, reconsideration and allowance of the pending claims are respectfully requested.

By this Amendment, Claims 1, 7, 9, 10, 11, 12, 15, 16 and 17 are amended and Claim 8 is canceled. The claims currently pending in this application are Claims 1-7 and 9-17, with Claims 1, 12 and 15 being the only independent claims.

Independent Claim 1 is directed to a catheter to be percutaneously inserted into a living body lumen. The catheter comprises a sheath portion having a lumen extending therein, an insertion member slidably disposed in the lumen of the sheath portion and having a distal end portion capable of protruding from a distal end portion of the sheath portion. In addition, an injection needle is disposed at the distal end portion of the insertion member for injecting a therapeutic composition into a target tissue in a living body. As set forth in amended independent Claim 1, an electrode is disposed at the distal end portion of the insertion member, and spaced from a bevel of the injection needle disposed at the distal end portion of the insertion member, for measuring a cardiac action potential.

Independent Claim 12 is directed to a catheter system comprising a catheter comprising a sheath portion having a lumen extending therein, an insertion member slidably disposed in the lumen of the sheath portion and having a distal end portion capable of protruding from a distal end portion of the sheath portion, and an injection needle disposed at the distal end portion of the insertion member for injecting a therapeutic composition into a target tissue in a living body. The catheter system further comprises, as amended above, a first electrode disposed at the distal end

portion of the insertion member and spaced from a bevel of the injection needle disposed at the distal end portion of the insertion member for measuring a cardiac action potential. Also provided is a second electrode for measuring the cardiac action potential and a puncture detection unit to which a conductor extending from the first electrode and a conductor extending from the second electrode are connected and which detects the puncture by the injection needle based on the cardiac action potential measured by the first electrode and the second electrode.

Finally, independent Claim 15 addresses a method of injecting a therapeutic composition by use of a catheter to be percutaneously inserted into a living body lumen, the catheter comprising a sheath portion having a lumen extending therein, an insertion member slidably disposed in the lumen of the sheath portion and having a distal end portion capable of protruding from a distal end portion of the sheath portion, an injection needle disposed at the distal end portion of the insertion member for injecting the therapeutic composition into a target tissue. As amended above, a first electrode is disposed at the distal end portion of the insertion member and spaced from a bevel of the injection needle disposed at the distal end portion of the insertion member for measuring a cardiac action potential. The method of Claim 15 comprises the steps of: (a) inserting the catheter into a living body and advancing the catheter to the vicinity of the target tissue; and (b) puncturing the target tissue by the injection needle and injecting the therapeutic composition into the target tissue through the injection needle, based on the cardiac action potential measured by the first electrode.

The Official Action sets forth an anticipatory rejection of independent Claims 1, 12 and 15 based on the disclosure in U.S. Patent No. 6,309,370 to *Haim et al.*

This document discloses a catheter 20 comprising a hollow needle 24 within the catheter's distal end 22 for injection of a drug into the myocardium. Referring to FIG. 1A, the needle is shown in a first configuration in which it is retracted into a sheath 26 inside the catheter 20, whereas in FIG. 1B, the needle extends distally out of distal end 22 for injection of the drug. The catheter 20 also comprises one or more contact sensors 36, i.e., pressure sensors, which generate signals responsive to contact between distal end 22 and the heart wall so as to assure proper contact between the catheter and the wall before extension of needle 24. The catheter 20 may also comprise one or more electrodes 38 which are used to measure electrical activity in the heart wall in order to assess and map the local viability of the heart tissue.

One difference between the claimed catheter recited in independent Claims 1, 12 and 15 and the disclosure in *Haim et al.* is that the electrodes in *Haim et al.* are disposed on the distal end of the sheath 26, not on the distal end of the hollow needle or spaced from a bevel of needle 24. In contrast, Claims 1, 12 and 15 recite that the electrode is disposed at the distal end portion of the insertion member, and spaced from a bevel of the injection needle disposed at the distal end portion of the insertion member, for measuring a cardiac action potential.

In *Haim et al.*, the electrodes 36 are disposed on the sheath for purposes of determining the surface contact between the sheath and the tissue surface and the electrodes 38 are disposed on the sheath for the purposes of assessing viability of the heart tissue prior to extension of the needle 24 out of the sheath 26, that is, prior to puncture. *Haim et al.* is not at all concerned with providing one or more electrodes to determine whether a needle has punctured the tissue. There would thus be no

reason to position the electrodes in the manner recited in the independent claims here. Further, considering the particular purpose for which the electrodes disclosed in *Haim et al.* are used (i.e., assessing whether or not the sheath is contacting the tissue surface and/or viability of the tissue prior to puncture), there would have been no reason to move the electrodes to arrive at the arrangement recited in independent Claims 1, 12 and 15. For at least that reason, it is respectfully submitted that independent Claims 1, 12 and 15 are patentably distinguishable over the disclosure contained in *Haim et al.*

With respect to the rejection of several dependent claims, the Official Action also makes specific reference to the embodiment of the apparatus shown in Fig. 3 of PCT Publication WO 99/04851 to *Shapland et al.*. *Shapland et al.* describes that the apparatus includes a guiding member 134 such as a catheter, with an inner member 140 slidably received in the guiding member 134. The distal end 145 of the inner member 140 is provided with a needle 148. *Shapland et al.* describes that this needle 148 functions as a first electrode 160. In addition, an un-illustrated electrically conductive band functioning as a second electrode is wrapped around the guiding member 134.

One difference between the claimed catheter recited in independent Claims 1, 12 and 15 and the disclosure in *Shapland et al.* is that the claimed catheter comprises an electrode disposed at the distal end portion of the insertion member and spaced from the bevel of the injection needle. The electrode 160 that is disposed on the needle in *Shapland et al.* is actually disposed on the bevel of the needle. With the arrangement disclosed in *Shapland et al.*, a change in impedance values can occur when the injection needle merely comes in contact with the tissue.

On the other hand, by arranging both of the electrode spaced from the bevel of the injection needle as recited in Claims 1, 12 and 15, it is possible to relatively reliably detect when the injection needle has been punctured into the tissue.

For at least the reasons set forth above, it is respectfully submitted that the catheter recited in independent Claims 1, 12 and 15 is patentably distinguishable over the disclosure in *Shapland et al.*

The Official Action sets forth a rejection of dependent Claim 8 (now incorporated into Claim 1) based on the disclosure in *Haim et al.* in view of the disclosure in U.S. Patent No. 6,391,005 to *Lum et al.*

*Lum et al.* discloses an apparatus having a sensor for sensing the depth of penetration of a needle into the tissue of a patient. *Lum et al.* discloses several embodiments involving a hypodermic needle 110, a solid needle assembly 126 and another hypodermic needle 134. In the case of the embodiment shown in FIGS. 5A and 5B, electrodes 148a, 148b are disposed on a bevel of an injection needle 144. Between the electrodes 148a, 148b, a non-conductive material 146 is sandwiched, and the injection needle 144 is thus solid, not hollow. In contrast, the injection needle according the claimed invention is hollow in order to inject a therapeutic composition into a target tissue, and the electrode is spaced from the bevel of the injection needle for measuring a cardiac action potential.

In the case of the hypodermic needle 110 shown in Fig. 2A, the needle is provided with an electrically conductive coating 122, having an end 125, and an electrically conductive wire 120 having an end 123. The conductive ends 123, 125 are provided near to the distal end for sensing an impedance change indicating the desired penetration has been achieved. In addition, the conductive end 123 is

disposed on the bevel while the conductive end 125 abuts the bevel. The claimed invention recited in claim 1 has no electrode on the bevel of the injection needle as the electrode is recited as being spaced from the bevel of the injection needle. The electrodes in *Lum* are disposed on the bevel of the injection needle and at an outer circumferential surface of the insertion member for sensing an impedance of the skin tissue layer, which changes in response to the puncture depth. On the other hand, in the claimed catheter of Claim 1, securely puncturing the target tissue by the injection needle is confirmed based on the detection of a change in the cardiac action potential for the injection of the therapeutic composition into the target tissue. Accordingly, for the purposes of securely puncturing the target tissue, it is preferable not to dispose the electrode at the bevel of the injection needle.

For at least the reasons set forth above, Applicants submit that the prior art relied upon by the Examiner do not disclose or suggest an electrode disposed at the distal end portion of the insertion member and spaced from the bevel of the injection needle disposed at the distal end portion of said insertion member for measuring a cardiac action potential.

The dependent claims are allowable at least by virtue of their dependence from allowable independent claims. Thus, a detailed discussion of the additional distinguishing aspects recited in the dependent claims is not set forth at this time.

## CONCLUSION

In view of the above amendments and remarks, Applicants respectfully submit that the claims of the present application are now in condition for allowance, and an early indication of the same is earnestly solicited.

Should any questions arise in connection with this application or should the Examiner believe that a telephone conference would be helpful in resolving any remaining issues pertaining to this application; the Examiner is kindly invited to call the undersigned counsel for Applicant regarding the same.

Respectfully submitted,

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